

04-00-0003—VENDING MACHINES

The sale of any legend drugs or medicines by means of a coin-operated vending machine is expressly prohibited. (10/09/80)

04-00-0004—RE-USE OF DRUGS PROHIBITED

The reuse of returned portions of a prescription drug for human consumption is prohibited whether dispensed by order of a prescription or otherwise. (10/09/80)

04-00-0005—PICK UP STATIONS

No person, firm, or business establishment shall offer to the public, in any manner, their services as a "pick-up-station" or intermediary for the purpose of having prescriptions filled or delivered, whether for profit or gratuitously. Nor may the owner of any pharmacy or drug store authorize any person, firm, or business establishment to act for them in this manner—provided however, intermediary delivery stations after approval by the Board may be operated in clinics in which a practitioner is in attendance at least one day per week and located in an area where pharmaceutical services are unavailable within ten miles of the clinic provided the filled prescriptions are delivered to a designated representative of the pharmacist filling the prescription. (10/09/80, Amended 2/17/82, and 8/19/99)

04-00-0006—EMERGENCY PHARMACY SERVICES

Any pharmacy providing prescription drugs to one or more patients in a nursing home or other institution shall provide emergency prescription services for those patients and shall provide information to the nursing home or institution indicating how the pharmacists can be reached after pharmacy hours.

All pharmacies (other than hospital and institutional) who do not provide emergency drug services for non-institutionalized patients shall post a sign at least 8½ by 11" with letters of at least one (1) inch stating "This pharmacy will not provide emergency prescription drugs when the pharmacy is closed." (6/25/83)

04-01: PHARMACY PERMIT FEES

04-01-0001—PERMIT FEES

Any person, corporation or partnership operating a pharmacy in this state desiring to continue such operation must pay a fee for a permit as established by law and/or regulation. If the fee is not paid on or before February 1st of any year, a penalty as defined in regulation 01-00-0007 shall be levied for each month the pharmacy permit fee is delinquent. If the permit fee is unpaid by April 1st of any year, the licensed pharmacy shall be expunged from the records of the State Board of Pharmacy, and the owner and/or pharmacist in charge thereof shall, within thirty days, remove all drug signs and legally dispose of all prescription legend drugs. (10/9/80, amended 6/13/85, amended 6/20/91 & 8/23/96)

04-02: REGULATIONS REGARDING RETAIL PHARMACIES

04-02-0001—APPLICATIONS FOR PHARMACY PERMITS

~~Pharmacies shall apply for licensure and renewal on forms provided by the Board. Licensed pharmacy permits will be considered by the Board staff upon written application in such forms as~~

~~may be adopted by the Board.~~ The permit will be issued to qualified applicants in the name of the licensed pharmacist who shall be directly responsible to the Board of Pharmacy for the operation of the prescription department. (Revised 10/2003)

04-02-0002—REQUIREMENTS FOR A NEW PHARMACY PERMIT

Applications for pharmacy permits, other than annual renewal of existing permits, will be reviewed by the Board of Pharmacy Staff. No pharmacy may open for business within thirty (30) days of submission of the original application. Applications for a pharmacy permit for a new pharmacy must have the name and license number of the pharmacist in charge at the time of submission and cannot be altered except by submission of an application for change of pharmacist in charge and the fee as defined in regulation 01-00-0007. The pharmacist in charge of the new pharmacy application cannot be the pharmacist in charge of another pharmacy at the time of submission of the new pharmacy application. If a post office box is used as the address for the pharmacy, the actual street address must also be included on the application. The Executive Director may require that a representative of the owner(s) and the pharmacist in charge appear before the Board of Pharmacy to finalize the application. After review by the Board of Pharmacy staff, an "Inspection Request Form" will be sent to the address given as that of the owner(s) of the pharmacy making application. The inspection request form must be received in the Board of Pharmacy office at least one week before the facility will be ready for inspection.

Upon approval of the inspection of the physical facility by the Board of Pharmacy inspector, the Executive Director will complete the final approval of the application and the permit number will be issued.

04-02-0003—LEASED OPERATIONS—PHARMACY IS A DEPARTMENT OF ANOTHER BUSINESS

- (a) In any building, firm, or place of business where the pharmacy is a leased operation, and/or in situations where the pharmacist in charge does not own a substantial part of the business and is not manager of the total operation, and/or where the pharmacy is a department in a larger business that is not a drugstore or pharmacy, the prescription department shall be completely separated from the remainder of the building by some type of partition and said department shall be arranged and constructed so that the public will not have access to any legend drugs or medicine.
- (b) The prescription area or department of any pharmacy, firm or place of business must be constructed so that it may be locked to prevent unauthorized persons from entering it in the absence of a licensed pharmacist (or other authorized prescription personnel.)
- (c) A copy of the signed lease must be submitted with the application of the original permit, and at such other times as the original lease is changed or renewed.

04-02-0004—NECESSARY EQUIPMENT REQUIRED

No pharmacy permit shall be issued or continued for the conduct of a pharmacy unless the premises are equipped with the necessary appliances for maintenance of proper sanitation and kept in a clean, sanitary and orderly manner.

04-02-0005—PHARMACIST IN CHARGE

- (a) Pharmacists employed and in charge of pharmacies or drugstores, are required to notify the Board of Pharmacy and surrender for cancellation the permit issued in their names immediately

- (2) Refrigerator;
- (3) Single or multiple channel scintillation counter with well-type NaI(Tl) or Ge(Li) detector;
- (4) Radiochemical fume hood and filter system with suitable air sampling equipment;
- (5) At least two GM survey meters (including one high-range meter);
- (6) Microscope and hemacytometer;
- (7) Supplies to perform quality assurance testing;
- (8) Syringe and vial radiation shields;
- (9) Lead-shielded drawing station;
- (10) Decontamination supplies;
- (11) Supplies to perform quality assurance testing;
- (12) Lead transport shields for syringes and vials; and
- (13) D.O.T. approved USA Type A, 7A approved transport containers and other labels and supplies for shipping radioactive materials. (10/14/98)

04-03 REGULATIONS REGARDING RETAIL SPECIALTY PHARMACIES

04-03-0001—SPECIALTY PHARMACY PERMITS

The Board may issue a specialty pharmacy permit for a facility to provide unique aspects of pharmaceutical care to an identified patient population as provided in regulation 04-03-0001 *et seq.* Said specialty pharmacies and the pharmacists practicing therein shall comply with applicable federal and state laws and regulations, including Arkansas Pharmacy Law, A.C.A. § 17-92-101 *et seq.*, and Board Regulations, including without limitation regulations regarding retail pharmacies 04-02-0001 *et seq.*, which are not expressly superseded by the regulation applicable to the specific type of specialty pharmacy.

04-03-0002 METHADONE CLINIC SPECIALTY PHARMACY PERMIT

(a) Definitions:

- (1) “Methadone clinic pharmacy” means the place in which a licensed professional prepares methadone or buprenorphine to be administered and/or dispensed to a patient of the clinic.
- (2) “Dispensing methadone” means the preparation of one or more doses of methadone or buprenorphine in properly labeled, patient specific containers and delivery of said drugs to the patient to consume away from the clinic; only a licensed pharmacist or physician holding a dispensing permit issued by the Arkansas State Medical Board shall dispense methadone.
- (3) “Administering” means giving a single dose of methadone or buprenorphine to a patient to consume on-site; a physician shall administer or supervise the administration of methadone and the clinic pharmacist shall retain appropriate methadone administration records.

(b) Permit

- (1) Applications for methadone clinic permits shall be submitted pursuant to regulation 04-02-0001.
- (2) Any pharmacist shall notify the Board of Pharmacy in writing and ascertain that a methadone clinic pharmacy permit has been issued to the clinic before beginning practice in that clinic.

(c) Pharmacy operations

- (1) The pharmacist in charge shall provide written policies, procedures, and protocols for the operation of the pharmacy and shall obtain the approval of same by the Executive Director of the Pharmacy Board prior to operation of said pharmacy.
 - (2) A methadone clinic pharmacy shall stock and dispense methadone or buprenorphine only.
- (d) Physical Facilities
- (1) The pharmacy shall be a controlled area for the storage, safeguarding, preparation, and dispensing of methadone, a Schedule II narcotic, and buprenorphine, a Schedule III controlled substance, and shall have adequate facilities for pharmaceutical services including the procurement, storage, distribution, security and control of said drug consistent with all federal and state laws and regulations.
 - (2) The pharmacy shall have all equipment necessary to carry out the functions of the methadone clinic pharmacy and is otherwise exempt from regulation 02-02-0004; the equipment must be identified in the policies and procedures of each methadone clinic specialty pharmacy.
- (e) Licensed pharmacist personnel requirements
- (1) A methadone pharmacy shall be open to serve its patients, with a pharmacist or pharmacists on duty, a minimum of ten (10) hours per week or, if necessary, a greater period of time in order to perform pharmacy duties necessary to ensure patient safety.
 - (2) The pharmacy's operating hours must be approved by the Executive Director of the Arkansas State Board of Pharmacy. (Revised 10/2003)

04-04: OUT OF STATE PHARMACIES

04-04-0001—OUT OF STATE PHARMACY REGULATION

Out of State pharmacies shall comply with the following qualifications to be, and remain, licensed in Arkansas by the Board.

- (a)
 - (1) The pharmacy holds a current license in good standing in the state(s) in which it is located.
 - (2) Each pharmacist dispensing drugs into Arkansas shall be licensed as a pharmacist in Arkansas or in the state where he practices if that state has standards of licensure at least equivalent to those of Arkansas.
- (b) A pharmacist licensed in Arkansas shall be named in the application as the pharmacy's pharmacist in charge for the Arkansas permit and as the contact person for communications by the Board. Said Arkansas Pharmacist shall be an employee of the out of state pharmacy who is present at the pharmacy's physical location as stated on the out of state pharmacy permit. The pharmacist in charge for the Arkansas Permit need not be the same person as the pharmacist in charge of the pharmacy pursuant to the law in the state in which the pharmacy is located.
 - (1) That pharmacist will be responsible for receiving and maintaining publications distributed by the Board.
 - (2) If at anytime the pharmacist so designated as the pharmacist in charge for the Arkansas permit shall leave the employment of the pharmacy, the pharmacy shall notify the Board within ten (10) calendar days and designate another Arkansas licensed pharmacist to perform this function within thirty (30) calendar days.
- (c) The out of state pharmacy shall apply for licensure and renewal on forms approved provided by the Board. The Board may require such information as reasonably necessary to carry out the provisions of A.C.A. §17-92-401, including, without limitation, the name, address and position

of each officer and director of a corporation or of the owners if the pharmacy is not a corporation.

Provided, however, the Board may grant an exemption from licensing under A.C.A. §17-92-401 upon application by any non-resident pharmacy which confines its dispensing activity to isolated transactions. In determining whether to grant an exemption, the Board shall consider:

- (1) The number of prescriptions dispensed or reasonably expected to be dispensed into Arkansas.
 - (2) The number of patients served or reasonably expected to be served in Arkansas.
 - (3) Whether the pharmacy has promoted its services in Arkansas.
 - (4) Whether the pharmacy has a contract(s) with any employer(s) or organization(s) to provide pharmacy services to employees or other beneficiaries in Arkansas.
 - (5) Medical necessity.
 - (6) The effect on the health and welfare of persons in Arkansas.
 - (7) Any other relevant matters.
- (d) The pharmacy shall pay an annual license fee as defined in regulation 01-00-0007. When there is a change of Arkansas licensed pharmacist in charge, the fee for said change shall be paid as defined in regulation 01-00-0007. Final notification, to the Arkansas State Board of Pharmacy, of the new Arkansas licensed pharmacist in charge shall be on a form furnished by the Arkansas State Board of Pharmacy and accompanied by the fee for said change.
 - (e) The pharmacy shall maintain records of drugs dispensed to Arkansas addresses in such a manner so as to be readily retrievable upon request. These records shall be made available for inspection by the Board or by Arkansas law enforcement authorities.
 - (f) The pharmacy shall timely respond to any request for information from the Board or law enforcement authorities.
 - (g) The pharmacy shall maintain an incoming toll free telephone number for use by Arkansas customers to be answered by a pharmacist with access to patient records. This service shall be available a minimum of 40 hours a week, six days per week during normal business hours. This telephone number plus others available for use shall be printed on each container of drugs dispensed into Arkansas. The toll free number shall have sufficient extensions to provide reasonable access to incoming callers.
 - (h) Generic drugs shall be dispensed into Arkansas pursuant to the Arkansas Generic Substitution Act; provided, however, nothing herein shall be construed to mandate that an out of state pharmacy comply with the Arkansas Generic Substitution Act if such compliance would cause the out of state pharmacy to violate the Generic Substitution Act of the state wherein the facility of the dispensing out of state pharmacy is located.
 - (i) The facilities and records of the pharmacy shall be subject to inspection by the Board: provided, however, the Board may accept in lieu thereof satisfactory inspection reports by the licensing entity using similar standards of the state where the pharmacy is located.
 - (j) Each out of state pharmacy doing business in Arkansas by dispensing and delivering or causing to be delivered prescription drugs to Arkansas consumers shall designate a resident agent in Arkansas for service of process.
 - (k) Each out of state pharmacy doing business in Arkansas shall comply with Board of Pharmacy regulation 09-00-0001 (Patient Information, Drug Use Evaluation, and Patient Counseling).

Nothing herein shall be construed to mandate that an out of state pharmacy comply with Board regulation 09-00-0001 if such compliance would cause the out of state pharmacy to violate law or regulation of the state wherein the facility of the dispensing out of state pharmacy is located. (10/09/90, Revised 04/10/92, 6/23/96, 8/23/96, and 10/12/99).

04-05: REGULATIONS REGARDING HOSPITAL PHARMACIES

04-05-0001—HOSPITAL PHARMACEUTICAL SERVICES PERMIT

- (a) Any pharmacist practicing in an Arkansas hospital must so notify the Board of Pharmacy and ascertain that a hospital pharmaceutical services permit has been issued. The hospital pharmaceutical services permit shall be issued in the name of the hospital showing a pharmacist in charge.
- (b) Any hospital holding a retail pharmacy permit as of February 15, 1975, upon application for renewal must separate the facilities, stocks, records, etc., in compliance with A.C.A. 17-92-403-17-92-405.

All hospitals shall have adequate provisions for pharmaceutical services regarding the procurement, storage, distribution, and control of all medications. All federal and state regulations shall be complied with.

(1) Definitions

- (A) "Hospital pharmacy" means the place or places in which drugs, chemicals, medicines, prescriptions, or poisons are prepared for distribution and administration for the use and/or benefit of patients in a hospital licensed by the Arkansas Department of Health.

"Hospital pharmacy" shall also mean the place or places in which drugs, chemicals, medicines, prescriptions or poisons are compounded for the dispensing to hospital employees, members of the immediate families of hospital employees, patients being discharged, and other persons in emergency situations.

"Hospital pharmacy" shall also mean the provision of pharmaceutical services as defined in the Pharmacy Practice Act by a pharmacist to a patient of the hospital.

- (B) "Hospital employee" means any individual employed by the hospital whose compensation for services or labor actually performed for a hospital is reflected on the payroll records of a hospital.
- (C) "Qualified hospital personnel" means persons other than licensed pharmacists who perform duties in conjunction with the overall hospital pharmaceutical services for inpatients.
- (D) "Licensed pharmacist" means any person licensed to practice pharmacy by the Arkansas State Board of Pharmacy who provides pharmaceutical services as defined in the Pharmacy Practice Act to patients of the hospital.
- (E) "Unit dose distribution system" means a pharmacy-coordinated method of dispensing and controlling medications in hospitals in which medications are dispensed in single unit packages for a specific patient on orders of a physician where not more than a 24-hour supply of said medications is dispensed, delivered, or available to the patient.

"Unit dose distribution system" also means a system that meets the requirement of a "Unit Dose Distribution System," provided that up to a 72-hour supply may be sent to